UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,584	04/07/2006	Jallal Messadek	36193	9204

23589 7590 02/25/2010

HOVEY WILLIAMS LLP
10801 Mastin Blvd., Suite 1000
Overland Park, KS 66210

EXAMINER	
VU, JAKE MINH	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
02/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,584	MESSADEK ET AL.	
	Examiner	Art Unit	
	Jake M. Vu	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30 and 32-91* is/are pending in the application.

4a) Of the above claim(s) *14,28-30,32-74 and 82-91* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15-27 and 75-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/15/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Restriction Requirement Response filed on 11/13/2009; and Information Disclosure Statement filed on 04/15/2008.

- Claims 1-30, 32-91 are pending in the instant application.
- Claim 14 is drawn to non-elected specie.
- Claims 14, 28-30, 32-74, 82-91 are withdrawn from consideration.

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-27 and 75-81) and specie election of "glycine betaine anhydrous" in the reply filed on 11/13/2009 is acknowledged.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 16, 77-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The pharmaceutical derivatives and precursors do not meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus of derivatives and precursors of pharmaceutical encompassed by the claim, since there is no description of the structural relationship of these derivatives/precursors provided in the specification and Applicant has not provided a description as to how the base molecule may be changed while remaining a derivative/precursor.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 13, 16, 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1 and 16, what is the difference between the terms “lipidic betaines” versus “betaines lipid”? Please amend or clarify.

Regarding claim 1, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by

the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the claims recite the broad recitation “first compound selected among the group consisting acetylsalicylic acid, salicylic acid, and pharmaceutical derivatives”, and the claims also recite “said first compound expressed as acetylsalicylic acid” which is the narrower statement of the range/limitation.

Regarding claims 13 and 26, the term “substantially” is a relative term, which renders the claim indefinite. The term “substantially immediately” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what level of the closeness constitutes of “substantially”. Therefore, one would not know what are the metes and bounds of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16, 18-27 rejected under 35 U.S.C. 102(b) as being anticipated by GUINOT (US 4,703,045).

Applicant's claims are directed to a composition comprising of: acetylsalicylic acid; betaine glycine salt. Additional limitations include: betaine glycine salt is 5 times the amount of acetylsalicylic acid; dry particles; at least one compound reacting in presence of water.

GUINOT teaches a composition comprised of: acetylsalicylic acid (see col. 6, line 52-53); and betaine glycine salt (see col. 6, line 65-66). Additional disclosures include: 2g of betaine and 0.2g of acetylsalicylic acid (see col. 6, line 63-66), which reads on betaine glycine salt is 5 times the amount of acetylsalicylic acid; soluble powder (see col. 6, line 63), which reads on dry particles; and sorbitol (see col. 6, line 67), which reads on at least one compound reacting in presence of water; effervescent tablet (see col. 6, line 32 and 44), which reads on porous carrier; general maximum adult dosage of betaine salt is 24 and acetylsalicylic acid is 400mg (see col. 6, line 10-15), which is 60 times the amount of betaine versus acetylsalicylic acid; effective amount of acetylsalicylic acid (see col. 5, line 52-53); other betaine salt con be used (see col. 5, line 65-67).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13, 15-27, 75-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over GUINOT (US 4,703,045) in view of LACY et al (Drug Information Handbook (1999-2000), pg. 90-92) and ARMAND et al (US 6,531,171).

As discussed above, GUINOT teaches a composition comprised of: acetylsalicylic acid (see col. 6, line 52-53); and betaine glycine salt (see col. 6, line 65-66). Additional disclosures include: 2g of betaine and 0.2g of acetylsalicylic acid (see col. 6, line 63-66), which reads on betaine glycine salt is 5 times the amount of acetylsalicylic acid; soluble powder (see col. 6, line 63), which reads on dry particles; and sorbitol (see col. 6, line 67), which reads on at least one compound reacting in presence of water; effervescent tablet (see col. 6, line 32 and 44), which reads on porous carrier; general maximum adult dosage of betaine salt is 24 and acetylsalicylic acid is 400mg (see col. 6, line 10-15), which is 60 times the amount of betaine versus acetylsalicylic acid; effective amount of acetylsalicylic acid (see col. 5, line 52-53); other betaine salt con be used (see col. 5, line 65-67).

GUINOT does not teach using less than 60mg of acetylsalicylic acid or glycine betaine anhydrous.

LACY teaches aspirin, which is acetylsalicylic acid, as low as 60mg and 65mg were used in the prior art (see pg. 92, under Dosage Forms).

ARMAND teaches glycine betaine anhydrous and the salt forms are commercially available (see col. 4, line 8-23).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate 60mg or 65mg of acetylsalicylic acid into GUINOT's composition. The person of ordinary skill in the art would have been motivated to make those modifications, because these are effective dosage of acetylsalicylic acid, and reasonably would have expected success because GUINOT teaches using effective dosage of acetylsalicylic acid.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate glycine betaine anhydrous into GUINOT's composition. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because glycine betaine anhydrous is a functional equivalent of betaine compounds.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as a

lower dosage for geriatric patients, since they metabolize drugs slower. Thus, a lower dosage would be still be an effective dosage. Therefore, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618